



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

33461d

One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

WARNING LETTER

NWE-25-02W

July 30, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alan Blair
AffordableHGH.com
Top Management Co.
5 River Road, #105
Wilton, CT 06897

and

51 Mayflower Dr
Wilton, CT 06897

Dear Mr. Blair,

This letter concerns **somatotropin (rDNA origin) with cyanocobalamine and pyridoxine for injection** compounded by your firm. Somatotropin is also known as recombinant human growth hormone (hGH) and is currently marketed by your firm as shown on your Internet sites www.affordablehgh.com and www.buyhghdirect.com. According to information on these sites, your compounded hGH product is being promoted as part of an anti-aging treatment regimen. This activity is in violation of 21 U.S.C. 333(f).

The intended anti-aging treatment regimen use for your compounded hGH product is conveyed through claims on both of your Internet sites. These include statements such as "...fountain of youth flows from needle...Human growth hormone (hGH) replacement therapy is one of the most promising of all the anti-aging treatments...six months of hGH replacement therapy can reverse several bio-markers of aging by ten to twenty years...effects of human growth hormone therapy include: decreased body fat, increased lean mass, increased bone density, increased energy levels, improved skin tone and texture, improved immune system function, and a greater sense of well-being...hGH (preferably bio-engineered, recombinant hGH) called "Somatotropin" produces measurable health, anti-aging, and rejuvenation benefits....lowered blood

pressure and cholesterol...improved sleep patterns... enhanced sexual drive and performance...regeneration of heart, liver and kidney...improved skin tone and removed wrinkles..." Ordering instructions are contained on your web sites and your sites will automatically refill the prescription, and bill and ship the compounded hGH product on a monthly basis, until the purchaser logs in and suspends or cancels the subscription to the prescription.


Distribution of your hGH product violates 21 U.S.C. 333(f). Your hGH product is being promoted and distributed for an unapproved use. There are no recombinant hGH products that are approved by the Food and Drug Administration (FDA) for anti-aging treatment. 21 U.S.C. 333(f) states that "...whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under 21 U.S.C. 355 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, United States Code, or both."

This letter is not intended to be an all-inclusive review of your Internet sites and the products your firm may market. The violations of the Act described above are not intended to be an all-inclusive list of the deficiencies of you and your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with Federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure, injunction, and/or prosecution.

We request that you reply in writing within fifteen (15) days of your receipt of this letter stating the action your firm will take to discontinue marketing of this drug product. Your response should be directed to Mark Lookabaugh, Compliance Officer, at the U.S. Food and Drug Administration, One Montvale Ave., 4th Floor, Stoneham, MA 02180.

Sincerely yours,



Gail T. Costello
Director
New England District